Health Canada / Santé Canada

Part I: 23 pages + this one
Part II: 19 pages + this one
This is ——> Part III: 19 pages + this one

PROGRAMME DES PRODUITS THÉRAPEUTIQUES
THERAPEUTIC PRODUCTS PROGRAMME

NOTRE MISSION: Faire en sorte que les médicaments, les matériels médicaux et les autres produits thérapeutiques disponibles au Canada soient sûrs, efficaces et de haute qualité.

OUR MISSION: To ensure that the drugs, medical devices and other therapeutic products available in Canada are safe, effective and of high quality.

Visit our Website at / Visitez notre site Internet
www.hc-sc.gc.ca/hpb-dgps/therapeut

CONTINUING ASSESSMENT DIVISION / DIVISION DE L'ÉVALUATION CONTINUE
BUREAU OF DRUG SURVEILLANCE / BUREAU DE LA SURVEILLANCE DES MÉDICAMENTS
FINANCE BUILDING / ÉDIFICE FINANCE
FIRST FLOOR / 1er ÉTAGE
OTTAWA (ONTARIO)
K1A 1B9
ADDRESS LOCATOR -0201C1 - INDICE DE L'ADRESSE
FAX: (613) 957-0335

TO/À: Robert Seidman

FAX: 1(818) 712-6482
TEL: (818) 610-4817
DATE: April 13, 1999

NUMBER OF PAGES TO FOLLOW: 61
NOMBRE DE PAGES À SUIVRE:

MESSAGE/MESSAGE:

Dear Mr. Seidman,

This is further to your fax dated December 16, 1998 requesting information on suspected adverse drug reactions (ADRs) associated with the use of cetirizine, fexofenadine and loratadine. We apologize for the delay.

A search of the national database was performed for all the suspected adverse reactions associated with these suspected drugs. The attached printouts outline the results. These printouts cover the time period since marketing until April 12, 1999. There may be reports which have been received by the program which are not yet entered into the database. Kindly direct your attention of all persons using these printouts to the following Caveat:

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Protection Branch is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Protection Branch scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization.

If you have any further questions, please do not hesitate to contact me.

Pascale Springuel

Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Fexofenadine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116264		-	Female					Unknown
	ALLEGRA					Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0116365		-	Female					Recovered without sequelae
	ALLEGRA				1 Day(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	VISION DISORDERS					LACRIMATION ABNORMAL		
0116366		43 Year(s)	Male					Recovered without sequelae
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	VISION DISORDERS					LACRIMATION ABNORMAL		
0116367		24 Year(s)	Female					Not yet recovered
	ALLEGRA				12 Day(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					EYE IRRITATION		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization. Produced by: Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116368		27 Year(s)	Male					Not yet recovered
	ALLEGRA				12 Day(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	VISION DISORDERS					EYE IRRITATION		
	DECONGEST NASAL SPRAY					Concomitant		
0116375			Female					Not yet recovered
	ALLEGRA				1 Day(s)	Suspected	1 Dosage form	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	SKIN AND APPENDAGES DISORDERS					PRURITUS		
	SKIN AND APPENDAGES DISORDERS					ITCHING		
	BODY AS A WHOLE - GENERAL DISORDERS					OEDEMA		
0116378			Male					Unknown
	ALLEGRA					Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					EYE IRRITATION		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					HEADACHE		
0116379			Male					Unknown
	ALLEGRA					Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116380		27 Year(s)	Male					Unknown
	ALLEGRA				Continuing on Drug	Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	REACTINE					Other		
0116381		45 Year(s)	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0116382		13 Year(s)	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	VISION DISORDERS					EYE IRRITATION		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION		
0116383		40 Year(s)	Female					Recovered without sequelae
	ALLEGRA				9 Day(s)	Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	VISION DISORDERS					EYE IRRITATION		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	FLONASE					Treatment		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116384		18 Year(s)	Female					Recovered without sequelae
	ALLEGRA				9 Day(s)	Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	VISION DISORDERS					EYE IRRITATION		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	FLONASE					Treatment		
0116385			Female					Not yet recovered
	ALLEGRA				1 Week(s)	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					EYE IRRITATION		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	ANTI-HYPERTENSIVE					*Concomitant*		
0116386		37 Year(s)	Female					Not yet recovered
	ALLEGRA				2 Day(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION		
	RESPIRATORY SYSTEM DISORDERS					THROAT IRRITATION		
	BODY AS A WHOLE - GENERAL DISORDERS					FEELING OF WARMTH		
	BODY AS A WHOLE - GENERAL DISORDERS					CONDITION AGGRAVATED		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	ACETAMINOPHEN					Concomitant		
	PROZAC					Concomitant		
	RIVOTRIL					Concomitant	0.5 Milligrams	
	XANAX					Concomitant	As necessary	

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116387		-	Female					Unknown
	ALLEGRA					Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0116388		26 Year(s)	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
0116389		-	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	CLARITIN					Other		
	REACTINE					Other		
0116394		-	Female					Unknown
	ALLEGRA					Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0116399		30 Year(s)	Male					Not yet recovered
	ALLEGRA				3 Day(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	VISION DISORDERS					EYE IRRITATION		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116400		18 Year(s)	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	VISION DISORDERS					EYE IRRITATION		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	CLARITIN					Other		
	REACTINE					Other		
0116402		41 Year(s)	Female					Not yet recovered
	ALLEGRA				2 Day(s)	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	SYNTHROID					Concomitant	0.75 Milligrams Daily	
0116405		-	Female					Recovered without sequelae
	ALLEGRA				1 Week(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
0116406		-	Male					Recovered without sequelae
	ALLEGRA					Suspected	First dose	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					BREATHING DIFFICULT		
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA		
	RESPIRATORY SYSTEM DISORDERS					WHEEZES		
	OXYGEN					*Treatment*		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0116655		57 Year(s)	Male					Recovered with sequelae
	ALLEGRA				1 Month(s)	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					DYSPNOEA		
	HEART RATE AND RHYTHM DISORDERS					FIBRILLATION ATRIAL		
	BODY AS A WHOLE - GENERAL DISORDERS					CHEST PAIN		
	ORNADE					Concomitant		
	PROCAINAMIDE					Treatment	30 Milligrams	
	VERAPAMIL HCL					Treatment	80 3 Daily	
0116768			Female					Recovered without sequelae
	ALLEGRA				1 Week(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	REACTINE					Concomitant		
	SELDANE					Concomitant		
0116908			Female					Not yet recovered
	ALLEGRA				3 Day(s)	Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0116982		48 Year(s)	Female					Not yet recovered
	ALLEGRA				4 Day(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	ESTROGENS (ORAL)					Concomitant	0.625 Milligrams	
	MOTRIN					Concomitant		
	TYLENOL EXTRA STRENGTH					Concomitant		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0117437		36 Year(s)	Male					Unknown
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					SWELLING NON-INFLAMMATORY		
	SKIN AND APPENDAGES DISORDERS					HIVES		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0117596		27 Year(s)	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0117602			Male					Unknown
	ALLEGRA					Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0117627		30 Year(s)	Female					Recovered without sequelae
	ALLEGRA				2 Day(s)	Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					CHEST DISCOMFORT		
	BODY AS A WHOLE - GENERAL DISORDERS					HOT FLUSHES		
	HEART RATE AND RHYTHM DISORDERS					PALPITATION		
	DOXYCYCLINE					Concomitant		
0117633		31 Year(s)	Female					Unknown
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION		
	VISION DISORDERS					LACRIMATION ABNORMAL		

Canadian Adverse Drug Reaction Monitoring Program
Summary of Reported Adverse Drug Reactions
Active Ingredient: Fexofenadine
All Reports received and entered into database before April 12, 1999

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0117690		34 Year(s)	Male					Recovered without sequelae
	ALLEGRA					Suspected	60 Milligrams	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	HEART RATE AND RHYTHM DISORDERS					PULSE IRREGULARITY NOS		
0117730		33 Year(s)	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINORRHOEA		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	ACETAMINOPHEN WITH CODEIN				Continuing on Drug	Concomitant		
	CODEINE					Concomitant		
	DIMETAPP					Other		
0117743		23 Year(s)	Female					Not yet recovered
	ALLEGRA				5 Day(s)	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	SKIN AND APPENDAGES DISORDERS					ITCHING		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	VISION DISORDERS					RED EYE		
	BODY AS A WHOLE - GENERAL DISORDERS					PAIN		
	ACTIFED					Other		
0117819		34 Year(s)	Male					Not yet recovered
	ALLEGRA				3 Day(s)	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	RESPIRATORY SYSTEM DISORDERS					RHINORRHOEA		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0117840		13 Year(s)	Male					Not yet recovered
	ALLEGRA					Suspected	1 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization. Produced by: Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0117841		15 Year(s)	Male					Not yet recovered
	ALLEGRA					Suspected	1 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0117842		28 Year(s)	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	2	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0118121		18 Year(s)	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0118237		46 Year(s)	Male					
	ALLEGRA					Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					CONJUNCTIVAL CONGESTION		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0118263		-	Female					Unknown
	ALLEGRA				~1 Week(s)	Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0118331		35 Year(s)	Female					Recovered without sequelae
	ALLEGRA					Suspected	60 Milligrams First dose	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					DYSPNOEA		
	BODY AS A WHOLE - GENERAL DISORDERS					CHEST PAIN		
	HEART RATE AND RHYTHM DISORDERS					PALPITATION		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug
0118332		38 Year(s)	Female				
	ALLEGRA				~10 Day(s)	Suspected	60 Milligrams 2 D
	System Organ Class:					*WHO Adverse Reaction Term:*	
	RESPIRATORY SYSTEM DISORDERS					RHINITIS	
	VISION DISORDERS					CONJUNCTIVAL CONGESTIO	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF	
0118333		-	Female				
	ALLEGRA				~1 Month(s)	Suspected	120 Milligrams D
	System Organ Class:					*WHO Adverse Reaction Term:*	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF	
0118356		35 Year(s)	Female				
	ALLEGRA				1 Day(s)	Suspected	60 Milligrams 2 D
	System Organ Class:					*WHO Adverse Reaction Term:*	
	HEART RATE AND RHYTHM DISORDERS					TACHYCARDIA	
0118407		28 Year(s)	Female				
	ALLEGRA				5 Day(s)	Suspected	60 Milligrams 2 D
	System Organ Class:					*WHO Adverse Reaction Term:*	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF	
0118409		-	Female				
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams D
	System Organ Class:					*WHO Adverse Reaction Term:*	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF	
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE	
0118440		-	Female				
	ALLEGRA					Suspected	
	System Organ Class:					*WHO Adverse Reaction Term:*	
	BODY AS A WHOLE - GENERAL DISORDERS					SENSATION OF WARMTH	
	GASTRO-INTESTINAL SYSTEM DISORDERS					NAUSEA	
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					DIZZINESS	

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents t opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information c reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Onl proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. R by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data w within your immediate organization. Produced by: Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

	Outcome
	Unknown
2 Daily	
TION	
	Unknown
: Daily	
2 Daily	
	Not yet recovered
2 Daily	
	Unknown
: Daily	
	Unknown

its the suspicion,
in contained in these
Only a small
:. Reports submitted
ita will be used only

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0118538		72 Year(s)	Female					Recovered without sequelae
	ALLEGRA					Suspected	60 Milligrams First dose	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					CONVULSIONS		
	METAMUCIL					Concomitant		
	SYNTHROID					Concomitant	0.25 Milligrams	
0118552		28 Year(s)	Female					Recovered without sequelae
	ALLEGRA				6 Week(s)	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					CONVULSIONS		
	LAMISIL				Continuing on Drug	Concomitant		
	MARVELON				Continuing on Drug	Concomitant		
	SOFRACORT				Continuing on Drug	Concomitant		
	DILANTIN					Treatment	100 Milligrams 3 Daily	
0118604		13 Year(s)	Male					
	ALLEGRA				3 Day(s)	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0118607		13 Year(s)	Male					
	ALLEGRA				2 Week(s)	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0118734		-	Female					Recovered without sequelae
	ALLEGRA					Suspected	1 Dosage form First dose	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					DIZZINESS		
	VISION DISORDERS					VISION DOUBLE		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					WALKING DIFFICULTY		
	BETA-BLOCKING AGENTS					Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					DIZZINESS		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					WALKING DIFFICULTY		
	VISION DISORDERS					VISION DOUBLE		
	CODEINE					Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					VISION DOUBLE		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					DIZZINESS		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					WALKING DIFFICULTY		
	VALIUM					Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					DIZZINESS		
	VISION DISORDERS					VISION DOUBLE		
	CENTR & PERIPH NERVOUS SYSTEM DISORDERS					WALKING DIFFICULTY		
0118757		-	Female					
	ALLEGRA				6 Day(s)	Suspected		
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					CONJUNCTIVAL CONGESTION		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
0118816		-	Male					Unknown
	ALLEGRA				3-4 Day(s)	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0118856		25 Year(s)	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINORRHOEA		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					THROAT IRRITATION		
	VISION DISORDERS					EYE IRRITATION		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	ORAL CONTRACEPTIVES					Concomitant		
0118857			Male					Not yet recovered
	ALLEGRA				40 Day(s)	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINORRHOEA		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0118858		58 Year(s)	Female					
	ALLEGRA				Continuing on Drug	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	ELTROXIN				20 Year(s)	Concomitant		
	ESTRADIOL					Concomitant		
	VIVELLE				1 Year(s)	Concomitant		
0119143		30 Year(s)	Female					
	ALLEGRA				3 Day(s)	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					CONJUNCTIVITIS		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0119164		36 Year(s)	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	3 Dosage form	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0119231		27 Year(s)	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	VISION DISORDERS					LACRIMATION ABNORMAL		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
0119232		24 Year(s)	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION		
	VISION DISORDERS					EYE IRRITATION		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0119260		27 Year(s)	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0119329		-	Male					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	SKIN AND APPENDAGES DISORDERS					ITCHING		
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION		

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug
0119330		37 Year(s)	Female				
	ALLEGRA				9 Day(s)	Suspected	60 Milligrams 2 Da
	System Organ Class:					*WHO Adverse Reaction Term:*	
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF	
	SKIN AND APPENDAGES DISORDERS					ITCHING	
	RESPIRATORY SYSTEM DISORDERS					NASAL CONGESTION	
	PREMARIN					Concomitant	
	CLARITIN					Other	
	SELDANE					Other	
0119331		59 Year(s)	Male				
	ALLEGRA				4-5 Day(s)	Suspected	60 Milligrams 2 Da
	System Organ Class:					*WHO Adverse Reaction Term:*	
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF	
	SECONDARY TERMS					EYE BURNS	
	VITAMIN C					Concomitant	
	VITAMIN E					Concomitant	
	REACTINE					Other	
0119332		27 Year(s)	Female				
	ALLEGRA				6-7 Day(s)	Suspected	60 Milligrams 2 Da
	System Organ Class:					*WHO Adverse Reaction Term:*	
	RESPIRATORY SYSTEM DISORDERS					RHINORRHOEA	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF	
0119333		38 Year(s)	Female				
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams 2 Da
	System Organ Class:					*WHO Adverse Reaction Term:*	
	RESPIRATORY SYSTEM DISORDERS					RHINORRHOEA	
	VISION DISORDERS					LACRIMATION ABNORMAL	
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF	

Outcome
Not yet recovered
Not yet recovered
Not yet recovered
Not yet recovered

ion,
in these
bmitted
ed only

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0119440		44 Year(s)	Female					Not yet recovered
	ALLEGRA				10 Day(s)	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					RHINITIS		
	VISION DISORDERS					CONJUNCTIVITIS		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0119484		24 Year(s)	Male					Not yet recovered
	ALLEGRA				2 Day(s)	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	SELDANE					Other		
0119710		29 Year(s)	Female					Not yet recovered
	ALLEGRA				Continuing on Drug	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	RESPIRATORY SYSTEM DISORDERS					SNEEZING EXCESSIVE		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0119711		42 Year(s)	Female					Not yet recovered
	ALLEGRA				~1 Month(s)	Suspected	60 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
	INHALER THERAPY					Concomitant		
	CLARITIN					Other		
0120001		36 Year(s)	Male					Died drug may be contributory
	ALLEGRA					Suspected	60 Milligrams First dose	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	GASTRO-INTESTINAL SYSTEM DISORDERS					GAGGING		
	RESPIRATORY SYSTEM DISORDERS					COUGHING		

CAVEAT: The vast majority of reports on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of reports submitted. The information contained in these reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization. Produced by: Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome
0120002		28 Year(s)	Female					Recovered without sequelae
	ALLEGRA				~4 Day(s)	Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					EFFICACY, LACK OF		
0122329		57 Year(s)	Male					Recovered with sequelae
	ALLEGRA				~2 Month(s)	Suspected	120 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	BODY AS A WHOLE - GENERAL DISORDERS					CHEST TIGHTNESS OF		
	HEART RATE AND RHYTHM DISORDERS					ATRIAL FIBRILLATION PAROXYSMAL		
	HEART RATE AND RHYTHM DISORDERS					PULSE RATE INCREASED		
	RESPIRATORY SYSTEM DISORDERS					BREATH SHORTNESS		
	ORNADE					Concomitant		
	PROCAINAMIDE					Treatment	30 Milligrams	
	VERAPAMIL					Treatment	5 Milligrams	
0122494		21 Year(s)	Female					Recovered without sequelae
	ALLEGRA				3-4 Day(s)	Suspected	240 Milligrams Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	MUSCULO-SKELETAL SYSTEM DISORDERS					MUSCLE PAIN		
	BODY AS A WHOLE - GENERAL DISORDERS					THORACIC PAIN		
0122508		61 Year(s)	Male					Recovered without sequelae
	ALLEGRA					Suspected	60 Milligrams 2 Daily	
	System Organ Class:					*WHO Adverse Reaction Term:*		
	HEART RATE AND RHYTHM DISORDERS					PULSE RATE INCREASED		
	HEART RATE AND RHYTHM DISORDERS					PALPITATION		
	DOXEPIN HYDROCHLORIDE					Concomitant	50 Milligrams Daily	
	DURALITH					Concomitant	300 Milligrams 2 Daily	
	FLUOXETINE					Concomitant	20 Milligrams Daily	
	GEMFIBROZIL					Concomitant	600 Milligrams 2 Daily	
	MODULON					Concomitant	100 Milligrams 3 Daily	
	PERCOCET					Concomitant	1 Dosage form 4 Daily	

Case report number	Drug name	Age	Sex	Dosage form	Duration of treatment	Drug Involvement	Dose of drug	Outcome

Total No. of reports 79

Total No. of reports with fatal outcome 1

CAVEAT: The vast majority of *reports* on which this summary is based are submitted by health practitioners and to a lesser extent laypersons. Each report represents the suspicion, opinion or observation of the individual reporter. Cause and effect relationships have not been established in the vast majority of *reports submitted*. The information contained in these reports to the Health Canada is raw information and has not been scientifically or otherwise verified as to cause and effect relationship by Health Canada scientists. Only a small proportion of suspected adverse reactions are reported to the program, consequently this information must not be used to estimate the incidence of adverse reactions. Reports submitted by pharmaceutical manufacturers are included in this summary. This summary contains unpublished data and is provided to you with the understanding that this data will be used only within your immediate organization. Produced by: Adverse Drug Reaction Reporting Unit, Bureau of Drug Surveillance, Therapeutic Products Programme.